China Pharmaceutical Guide

中国医药市场指南

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Written by:

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ABOUT THE AUTHOR

China Pharmaceutical Guide is authored by James J. Shen, a veteran of the Chinese healthcare industry and market, who has dedicated his entire 20-year career to pharmaceutical businesses in China.

James Shen has rich operational and senior level management experience on China's healthcare businesses in the capacities of a senior consultant to multinational pharmaceutical companies, a manager of joint venture projects and companies, a business development executive, an entrepreneur, and most recently a publisher.

James Shen started his career in the pharmaceutical industry in 1987 when he joined Beijing Ciba-Geigy Pharmaceutical Ltd. (now Beijing Novartis) as Assistant to the General Manager. While he studied MBA in England in various periods of 1980s, he worked as an editorial consultant for Scrip/PJB Publications, IMS and Financial Times Business Information on China's healthcare news.

In 1991, he founded W*i*CON International Ltd. in the USA to provide strategic consulting and competitive intelligence to international healthcare companies in order to assist and facilitate their market entry into China. He has worked with many large and mid-size international pharmaceutical companies on a diverse range of projects including entry strategy development, strategic alliances and joint ventures, marketing and distribution agreements, product registration and clinical trials, licensing and technology transfer, API sourcing, and M&A due diligence. His clients include *Pfizer*, *GD Searle*, *IVAX*, *Glaxo-SmithKline*, *Novartis*, *Sanofi-Synthelabo*, *TEVA*, *Taro*, *Ajinomoto*, *AL Pharma*, *IMS*, *Medical Economics/PDR*, *Mylan Pharmaceuticals*, *Polichem*, and *Merrill Lynch*.

As an entrepreneur, James Shen co-founded *Beijing Jicai Pharmaceutical Technologies Ltd.* in 1992, one of the first private pharmaceutical research institutions in China, and took over its management in 2001. He is also a co-founder of *Nanjing Zinox Pharmaceutical Co. Ltd.*, an emerging generic pharmaceutical company in China.

James Shen was the Managing Editor of the well-known *IMS China Update*, a monthly newsletter covering China's pharmaceutical market co-published by IMS and W*i*CON. He authored many China healthcare business publications in English throughout 1990s, including *Marketing Pharmaceuticals in China*, *Guide to Pharmaceutical Research Institutions in China*, and *Directory of Bulk Pharmaceutical Manufacturers & Products in China*.

In early 2006, following a restructure of his businesses, James Shen founded ***Pharma China***, now the most influential English media and source of business intelligence on China's pharmaceutical industry and market which is subscribed by most multinational pharmaceutical companies, CROs and investment banking firms active in China.

James Shen was educated in China, Europe and the USA at university and postgraduate levels, and received an MBA from the University of Exeter (UK) in 1990.

He is now based in the USA near New York City, New Jersey, Philadelphia and Washington DC, with frequent visits to China, Singapore and Europe. He continues to be active in strategic consulting with multinational pharmaceutical companies at the headquarter and regional head office levels.

PREFACE

Despite the enormous business opportunities and growth prospects offered by China's healthcare sector, I've witnessed and experienced countless regulatory and business environmental changes, which has frequently caused painful business difficulties, frustrations and downfalls, in my past 20 years of work in the sector as a consultant, manager and entrepreneur.

The ever-changing legal and market environments in China healthcare present the single biggest challenge to companies and executives operating in the sector. Naturally, many operational level issues and problems in the country also pose significant dangers to successful businesses.

Despite these challenges and difficulties, the Chinese pharmaceutical industry and market have achieved remarkable growth in the past two decades. The sector is generally developing towards a positive direction in the sense that it continues to grow steadily, its regulatory regime has become increasingly compatible with international standards with improving transparency, once rampant corruption is being tackled, its ongoing consolidation will eventually help establish order and stability, and the country's new healthcare reform will ultimately contribute to a more stable and healthier market environment.

There are success stories from all categoies of players, whether they are foreign or local, large or small, newcomer or established, private or state-owned. However, to be one of the success stories require firstly a thorough understanding of the sector, ability to face and tackle challenges, flexibility to deal with changes, and skills to maneuver through complex situations.

It has been my wish to put my experience and observation in the past 20 years operating in almost every aspect of China's pharmaceutical business into a publication, which will serve as a one-stop reference to anyone seeking to enter or operating in the Chinese pharmaceutical market. ***Packed with hard-to-find data and the author's expert knowledge from years of hard-earned experience in the industry, its comprehensiveness, practicality, insight, reliable data and analysis, and up-to-date information, are the features which sets this the guide apart from other publications with similar titles.***

This Guide is written based on my past experience, interviews with relevant industry experts and government officials, articles from Pharma China, information obtained from or published by Chinese government agencies, information obtained from or published by independent pharmaceutical industry associations, reliable data and information released exclusively to WiCON for publication from various reputable market research and consulting firms, information from other trustworthy trade journals and newspapers, related information found on the internet, and a large in-house information collection by WiCON International Group accumulated since 1986.

We would like to take the opportunity to thank all those organizations and individuals

who contributed to this publication and their continued cooperation is greatly appreciated.

About China Pharmaceutical Guide 2007

In this Guide, we will take our readers through some historical backgrounds, and the reform and development path that China's pharmaceutical sector has undergone since 1978. We will then discuss the varying estimates on the size of China's pharmaceutical markets (both ethical and OTC), and its different market segments, as well as drug consumption patterns in terms of therapeutic applications, regional differences, market shares between local and foreign companies, and more.

Contemporary challenges facing the pharmaceutical industry and market in China are reviewed, and potential opportunities are explored in the Guide. Understanding these challenges and opportunities will help foreign companies face the realities of China up close, be prepared for the turbulence ahead, and grasp the opportunities as they arise.

At present, 27 of the world's leading 30 multinational pharmaceutical companies have manufacturing and sales operations in China, and many of them have multiple operations. The Guide will review the current state of foreign investment in the Chinese pharmaceutical industry, and discuss the contemporary challenges facing international pharmaceutical companies in China.

The Guide also covers the healthcare provision and financing structure of the Chinese healthcare system, gives an overview of the Chinese pharmaceutical regulatory framework with briefings on each of the relevant important regulations, and offers introductions on each relevant government agencies with administrative and regulatory duties over the pharmaceutical industry.

Finally, the Guide includes a chapter that focuses on exploring pros and cons of various strategic approaches for market entry into China's burgeoning pharmaceutical market.

The 2007 Edition of China Pharmaceutical Guide was updated comprehensively with large amounts of latest data, statistics, tables and charts for 2006 and early 2007. In this new edition, a significant amount of new information is added, including case studies, profiles of major multinational pharmaceutical companies operating in China, more detailed coverage such as the Chinese vaccine and biopharmaceutical market segments, private hospital sector, and the API/bulk drug sector, as well as large amounts of new analytical reviews.

James J. Shen

June 8, 2007

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ADR – Adverse Drug Reaction

API – Active Pharmaceutical Ingredients

APP – Administrative Protection of Pharmaceuticals

AmCham – American Chamber of Commerce

CNCM – China National Corporation of Medicines

CNY – Chinese Yuan

CRO – Contract Research Organization

ED – Erectile Dysfunction

FDI – Foreign Direct Investment

FIE – Foreign Invested Enterprises

GCP – Good Clinical Practices

GDP – Gross Domestic Products

GLP – Good Laboratory Practices

GMP – Good Manufacturing Practices

GSP – Good Sales Practices

IFPMA – International Federation of Pharmaceutical Manufacturer Associations

JV – Joint Venture

M&A – Merger and Acquisition

MOH – Ministry of Health

MOLSS – Ministry of Labor and Social Security

MPC – Multinational Pharmaceutical Company

MR – Medical Representative

NBS – National Bureau of Statistics of China

NCGHSR - National Coordination Group for Healthcare System Reform

NDRC – National Development and Reform Commission

NPFPC – National Population and Family Planning Commission

OECD – Organization for Economic Co-operation and Development

OTC – Over The Counter

QA – Quality Assurance

PRC –People's Republic of China

R&D – Research and Development

RDPAC - R&D-based Pharmaceutical Association Committee

SATCM – State Administration of Traditional Chinese Medicine and Medicines

SDA – State Drug Administration

SFDA – State Food and Drug Administration

SIPO – State Intellectual Property Office

SMEI – Southern Medicine Economic Institute

SOE – State Owed Enterprise

SPAC – State Pharmaceutical Administration of China

STD – Sexually Transmitted Disease

TCM – Traditional Chinese Medicine

USFDA – US Food and Drug Administration

VAT – Value Added Tax

WM – Western Medicine

WHO – World Health Organization

WTO – World Trade Organization

EXECUTIVE SUMMARY

Official statistics suggest that the total revenues of China's pharmaceutical industry in 2006 was around CNY 500 billion (US$64 billion) with a total net profit of CNY 40.2 billion (US$5.2 billion), up by 17% and 10% respectively compared with the same figures in 2005.

Despite its continued rise, the growth rate of the Chinese pharmaceutical industry slowed significantly in 2006, and its profit margin fell by nearly 50%. 25.6% of the Chinese pharmaceutical companies made losses in 2006 and their total losses rose 26.2% compared with the same figure in 2005.

Estimates of the Chinese pharmaceutical market in 2006 range from US$15.1 billion by IMS to US$64 billion by official estimates, with various projections from a number of other sources in between.

WiCON's estimate on the overall Chinese drug market (including finished Western medicines, biochemical drugs, formulated traditional Chinese medicines and herbal drugs) in 2006 is about US$42 billion at ex-manufacturer prices (see Chapter II-1 for details).

Despite variances in market size estimates among different sources, one thing everyone agrees on is the growth of the Chinese pharmaceutical market. Most forecasts predict the market to grow at between 13% and 18% annually between 2006 and 2010.

These growth predictions are supported by an official estimate by the Development Research Center of China's State Council that based on current trends, health spending in the country is set to rise to 7-8% of GDP by 2010 from 5.7% in 2004, thus spurring further pharmaceutical market growth.

Continuous double-digit growth in the past two decades has convinced even the most conservative industry analysts to offer optimistic views about the future of the Chinese pharmaceutical market. Flashy news titles such as "China seen as fifth biggest drugs market by 2010" and "China could overtake the United States as the top drug market by 2050" are frequently seen in well-known papers and journals in recent years.

Indeed, these daring predictions are not unfounded and are supported by various broad economic evidences. Nevertheless, when taking a closer look at today's reality of the pharmaceutical industry in China, one may develop second thoughts about these predictions. In fact, challenges facing the pharmaceutical industry in China are threatening to derail it from the development fast track depicted by many observers.

Challenges Clouding the Future …

Despite all the positive forecasts and encouraging trends, the pharmaceutical industry in China, including both local firms and multinationals, is facing serious challenges that may potentially jeopardize the future prospects of the pharmaceutical market in the country.

- *Contradictions in Government Policies* - There is no doubt that the Chinese government's economic policies and systemic reform spurred the rise of the Chinese pharmaceutical industry and market. However, many structural problems in China's healthcare system and pharmaceutical sector remained in the past 25 years in exchange for faster short-term growth.

  On the one hand, the Chinese government wants the pharmaceutical industry to develop into an internationally competitive industry with strong new drug R&D capabilities, advanced technologies, and high quality standards; but on the other hand, it has cut back state investments in the pharmaceutical industry, repeatedly slashed prices of drug products and squeezed profit margins of the pharmaceutical industry through various cost containment measures.

  The government has also cut its healthcare spending sharply, forcing the medical industry to rely on profits from drug sales, hence making the pharmaceutical industry a major source of healthcare financing, and leading to many structural flaws in the healthcare system. Evidently the share of government healthcare spending in the country's total healthcare expenditures fell to 17.1% in 2004 from 36.2% in 1980. Meanwhile, the self-paid healthcare expenditures of urban Chinese residents rose 9.6 times between 1993 and 2005.

- *Changing Directions of Healthcare Reform* - A survey carried out by China Youth Daily in August 2005 found over 90% of the people in China were dissatisfied with the reform to the country's healthcare system in the previous 10 years. A heated discussion about China's healthcare reform began in May 2005 following the publication of a report by the Development Research Center under the State Council that concludes China's healthcare reform in the past two decades was largely unsuccessful.

  Consequently, the future direction of China's healthcare reform has now become a subject of heated public debate involving ordinary people, government officials, representatives of the National People's Congress and the media. In early 2007, the Chinese government entrusted seven sources, including the Development Research Center under the State Council, three prestigious universities, the World Bank, WHO and McKinsey & Co. to develop their proposals for the reform. It is likely the final plan will be determined sometime in the second half of 2007.

  The changing direction of the healthcare reform will have overwhelming and comprehensive impacts on the pharmaceutical industry, and is likely to trigger another round of restructuring of the industry.

- *Cost-containment Measures* - In its desperate attempts to control the rapidly rising healthcare expenditures, the Chinese government has introduced a matrix of cost-containment measures at national and local levels. These measures, including 23 rounds of price cuts on drug products by the central government, have seriously disturbed the normal operation and profit margin, causing sharp increases in administrative costs and resources, and substantially narrowing the profit margins of pharmaceutical companies, both local and foreign.

- *Intensive Competition and Industry Consolidation* - The Chinese pharmaceutical industry, which was once dominated by large state-owned enterprises, slowly disintegrated in the past 25 years into a large number of small enterprises with similar product portfolios. By 1985 there were only 1,377 pharmaceutical manufacturing companies in the country, but the number rose to nearly 4,000 in 2005 in spite of ongoing consolidation and compulsory GMP implementation.

  This has led to intensive competition and the rise of unethical and illegal practices in pharmaceutical sales and marketing. Cut-throat competition among local generic drug manufacturers has also resulted in shortening product life spans for generic drug products. Most local pharmaceutical companies are trapped in a vicious circle of low R&D investment, poor innovativeness and product differentiation, price competition and low profitability. Compounded by the effect of government price control and cuts, many pharmaceutical companies are suffering from heavy losses, and most small companies are expected to be out of business in the near future.

  The government's strategy to *"support the big, and let go of the small"* in recent years did not produce the desired result. Many large state-owned enterprises simply became bigger and fatter in size, rather than stronger, more competitive and more profitable. Valuable capital and resources drawn from the government and the stock market have been largely under-utilized without delivering expected performance.

- *Rising Conflicts between Local and Multinational Companies* - In the 1980s and early 1990s, local Chinese and multinational pharmaceutical companies had focused on the collaborative parts of their mutual relationships. The honeymoon period was over in the past decade, however, with both sides growing stronger in their own ways and beginning to concentrate more on the competitive parts of their relationships, leading to rising conflicts of interests between the two sides, especially in the area of IPR.

- *Rampant Counterfeit Drugs* - AmCham China estimated that between 10% and 15% of drugs sold through the retail channel in China are counterfeits. Not only do counterfeit and fake drugs pose serious public health problems for China, but also the country is now one of the biggest exporters of such products. In the past, drug counterfeiters in China developed poor quality fakes, but today they are producing high quality counterfeit drugs.

Multinational Pharmaceutical Companies Well-positioned for Future Growth

In spite of the turbulent market environment, MPCs have managed to establish a solid foothold and accumulated their business strength in China in the past few years.

During the period, MPCs consolidated their bases and organizations in the country, gained absolute control in their joint ventures, expanded sales and marketing networks, improved on IPR awareness and enforcement, quietly increased their influence over the Chinese government and its policies, and most importantly, successfully fostered an industrial and market environment that is now relatively more friendly to them.

MPCs also stepped up their investments in China to expand their capabilities in marketing and production in 2006 to prepare for future growth. In addition, MPCs began to establish selected R&D operations in China in order to take advantage of local talent pools, further strengthen ties with local communities and governments, and improve market access at the same time.

Outlook for the Chinese Pharmaceutical Market in future

Impacted by the regulatory swings last year, and coupled with more anticipated government corrective measures in 2007, the slowing growth of the Chinese pharmaceutical market in 2007 is likely to continue. The restructure and consolidation of the pharmaceutical industry in China are likely to intensify as a result of regulatory and market pressures.

In the short term, regulatory corrections and marketplace contractions seem inevitable. However, long term prospects of the Chinese market remain strong for those MPCs with patience. When the new healthcare reform takes a solid foothold, which may take a few years in the worst scenarios, a new marketplace with lasting stability and unprecedented market growth will emerge.

Future remains to be upbeat

As I am writing this summary, both Novartis and AstraZeneca are reporting their slower sales growth in China in 2006, but they remain upbeat about future with big plans for sharply increased investments in the country.

In conclusion, I would borrow a fairly recent Chinese proverb to describe the challenges and future outlook facing the pharmaceutical industry in China: “while the future is bright, the path to it is twisty with zigzags”.